UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,335	04/09/2004	Paul D. Wightman	58562US005	9992

32692 7590 09/15/2010

3M INNOVATIVE PROPERTIES COMPANY
PO BOX 33427
ST. PAUL, MN 55133-3427

EXAMINER	
DESAI, RITA J	

ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
09/15/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com
LegalDocketing@mmm.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PAUL D. WIGHTMAN, ISIDRO ANGELO E. ZARRAGA, NAIYONG JING, and JIE J. LIU

Appeal 2010-005037
Application 10/821,335
Technology Center 1600

Before ERIC GRIMES, JEFFREY N. FREDMAN, and STEPHEN WALSH, *Administrative Patent Judges.*

WALSH, *Administrative Patent Judge.*

DECISION ON APPEAL[1]

This is an appeal under 35 U.S.C. § 134(a) involving claims to an immune response modifier-support complex. The Patent Examiner rejected

---

[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

the claims as obvious and on the ground of non-statutory obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

STATEMENT OF THE CASE

The invention concerns immune response modifiers (IRMs) which "appear to act through basic immune system mechanisms known as toll-like receptors to induce selected cytokine biosynthesis and may be used to treat a wide variety of diseases and conditions." (Spec. 1, ll. 17-20). The IRM is covalently bonded to a macromolecular support material to form an IRM-support complex. (*Id.* at 1-2). The Specification explains that "the IRMs are still biologically active when attached to a support complex" and that such attachment "provides for the localized biological activity of the IRM...." (*Id.* at 2, ll. 17-26).

Claims 1, 3, 11, 12 and 14 are on appeal. Claims 1 and 11 are representative and read as follows:

1. An IRM-support complex comprising an IRM compound that is a TLR agonist selected from the group consisting of TLR6, TLR7, TLR8, and combinations thereof, and selected from the group consisting of imidazoquinoline amines; tetrahydroimidazoquinoline amines; and imidazopyridine amines; 1,2-bridged imidazoquinoline amines; 6,7-fused cycloalkylimidazopyridine amines; imidazonaphthyridine amines; tetrahydroimidazonaphthyridine amines; oxazoloquinoline amines; thiazoloquinoline amines; oxazolopyridine amines; thiazolopyridine amines; oxazolonaphthyridine amines; thiazolonaphthyridine amines; 1*H*-imidazo dimers fused to pyridine amines, quinoline amines, tetrahydroquinoline amines, naphthyridine amines, or tetrahydronaphthyridine amines; and combinations thereof; covalently bonded to a macromolecular support material.

11. The IRM-support complex of claim 1, wherein the macromolecular

support material has an average largest dimension of at least 1 nm.

The Examiner rejected the claims as follows:

• claims 1, 3, 11, 12 and 14 under 35 U.S.C. § 103(a) over Miller,[2] Gerster,[3] Slade[4] and Langer;[5] and

• claim 1 on the ground of non-statutory obviousness-type double patenting as unpatentable over claim 1 of Kedl.[6]

Claims 3, 12 and 14 have not been argued separately and therefore stand or fall with the claim 1. 37 C.F.R. § 41.37(c)(1)(vii).

OBVIOUSNESS

The Issue

The Examiner's position is Miller, Gerster and Slade each disclosed forms of IRMs that fell within the scope of claim 1. (Ans. 4). The Examiner found that the references disclosed using the IRMs for cytokine induction and to treat viral and neoplastic conditions. (*Id.*).

The Examiner found that Langer disclosed drugs, e.g., antitumor agents, covalently bonded to macromolecules for improved drug delivery. (*Id.*). The Examiner found that Langer taught that the drug complexes provided controlled release of the drug, localized delivery of the drug,

---

[2] US Patent No. 7,030,129 B2 issued to Richard L. Miller et al., Apr. 18, 2006.
[3] US Patent No. 4,689,338 issued to John F. Gerster, Aug. 25, 1987.
[4] US Patent No. 6,894,060 B2 issued to Herbert B. Slade, May 17, 2005.
[5] Robert Langer, *New Methods of Drug Delivery*, 249 SCIENCE, no. 4976, 1527-33 (1990).
[6] US Patent No. 7,427,629 B2 issued to Ross M. Kedl, Sep. 23, 2008.

increased comfort for the patient receiving the drug, improved compliance by the patient, and reduced need for follow-up care. (*Id.* at 5-6). Additionally, the Examiner found that Langer taught that the drug complex preserved the drug from being rapidly destroyed by the body. (*Id.*).

According to the Examiner, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to improve the drug delivery of the compounds of Miller, Gerster and Slade by using Langer's technique of covalently bonding the drug to a macromolecular support. (*Id.* at 8). The Examiner explained that the skilled artisan would have been motivated by Langer's teaching that forming a covalently bonded drug-support complex allows delivery of the drug to a specific location in a controlled manner while providing the patient increased comfort and improving patient compliance. (*Id.*).

Appellants do not dispute that Miller, Gerster and Slade each disclosed IRMs that fall within the scope of claim 1. Nor do Appellants dispute that Langer disclosed drugs covalently bonded to a macromolecular support material. Rather, Appellants contend that "none of the cited references teach or suggest (i) covalently attaching the IRM compounds of the current invention to a macromolecule or polymer or (ii) the surprising result that the presently claimed IRM compounds can remain functionally active while they are attached to a macromolecule or polymer." (*Id.* at. 8). According to Appellants, the prior art provided "no motivation or expectation of success in attaching IRMs to a solid support, or how to covalently attach the claimed IRMs to a solid support, or that one can preserve the activity of the IRM when attached to a solid support." (*Id.* at 10). Further, Appellants assert that the cited references do not disclose a

"macromolecular support material having an average largest dimension of at least 1 nm," as recited in dependent claim 11. (*Id.* at 9).

The issues with respect to this rejection are:

whether it would have been obvious to a person of ordinary skill in the art at the time the invention was made to prepare the drug-support complex disclosed by Langer using the IRM of Miller, Gerster or Slade as the drug;

whether Appellants have established that the claimed invention provided unexpected results sufficient to rebut a prima facie case of obviousness; and

whether the combined prior art taught or suggested using a macromolecular support material having an average largest dimension of at least 1 nm, as recited in claim 11.

Findings of Fact

1. We adopt the Examiner's specific findings of facts regarding the scope and content of Miller, Gerster, Slade, and Langer as set forth in the Answer. (*See* Ans. 4-7).

Principles of Law

The question of obviousness cannot be approached on the basis that an artisan having ordinary skill would have known only what was read in the references, because such artisan must be presumed to know something about the art apart from what the references disclose. *See In re Jacoby*, 309 F.2d 513, 516 (CCPA 1962). Moreover, the law presumes skill on the part of the

artisan rather than the converse. *See In re Sovish*, 769 F.2d 738, 742-43 (Fed. Cir. 1985).

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.,* 550 U.S. 398, 416 (2007). "If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *Id.* at 417.

It is well settled that unexpected results must be established by factual evidence. Mere argument or conclusory statements in the specification does not suffice. *In re Lindner,* 457 F.2d 506, 508 (CCPA 1972). A showing of unexpected results must be commensurate in scope with the breadth of the claims. *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983).

Analysis

We agree with the Examiner that it would have been obvious to a skilled artisan at the time of the invention to prepare a drug-support complex as disclosed in Langer using the IRM drugs disclosed in Miller, Gerster and Slade. The artisan would have been motivated by Langer's teaching that this drug complex advantageously improves drug delivery along with the ordinary skill in the chemical and pharmaceutical arts to attach a known IRM to a known macromolecular support according to a Langer's disclosed method, i.e., covalent bonding. Appellants have not established with persuasive evidence that doing so was beyond the skill of the ordinary artisan at the time of the invention. *See Jacoby*, 309 F.2d at 516; *see also Sovish*, 769 F.2d at 742-43.

Nor have Appellants established with persuasive evidence that the prior art IRMs would have been inactivated when covalently attached to a macromolecular support, or that Langer's disclosure would have suggested to an artisan at the time of the invention that such a result would have been expected. Indeed, Langer stated that "[p]olymers, such as polyethylene glycol (PEG), can be attached to drugs to either lengthen their lifetime or alter their immunogenicity." (*See* Ans. 5). Moreover, Langer did not limit its disclosure to any particular class or category of drugs such that a skilled artisan would not have been motivated or had a reasonable expectation of successfully applying Langer's teaching to an IRM.

For these reasons, we find that Examiner's rejection involved combining familiar elements according to known methods to yield a predictable, i.e., disclosed, result. *See KSR Int'l,* 550 U.S. at 416-17.

We find that Appellants have not established that the claimed invention provided unexpected results sufficient to rebut prima facie obviousness. According to Appellants, "the surprising result [is] that the claimed IRMs are able to remain active while covalently attached to a macromolecular support complex (claims 1, 3, and 11) or polymer (claims 12 and 14)." (App. Br. 6-7). Appellants support this contention with attorney argument and reference to Specification pages which simply state that "the IRM is biologically active during use while it is attached to the support." (*See* App. Br. 7 n. 10, citing Spec. 21). Conclusory statements are not the factual evidence required to establish unexpected results. *Lindner,* 457 F.2d at 508.

Moreover, as the Examiner explained, the claims do not recite any limitation requiring the IRM compound to be active or to remain active in

the complex. (Ans. 15). Thus, Appellants' asserted unexpected results are not commensurate in scope with the breadth of the claims. *See Grasselli*, 713 F.2d at 743.

Regarding claim 11, we agree with Appellants (App. Br. 9) that the Examiner has not established that the cited references taught or suggested that "the macromolecular support material has an average largest diameter of at least 1 nm." (*See* Claim 11). Consequently, we reverse the obviousness rejection of claim 11.

Accordingly, we affirm the obviousness rejections of claims 1, 3, 12 and 14, and we reverse the obviousness rejection of claim 11.

DOUBLE PATENTING

The Issue

The Examiner's position is that instant claim 1 and claim 1 of Kedl are not patentably distinct from each other. (Ans. 11). Specifically, the Examiner found that the instant claim is drawn to a complex of an IRM compound which is covalently bonded to a macromolecule and Kedl's claim 1 is also drawn to the same IRM compound which is bonded to an antigen, i.e., a macromolecule. (Ans. 11).

Appellants contend that the Examiner erroneously referenced US Patent No. 5,078,978 in the rejection, which patent "is not owned by 3M and is not drawn to the same subject material." (App. Br. 10). Further, Appellants assert that "the Examiner may have meant to cite to claim 1 of US Patent No. 7,427,629 [issued to Ross M. Kedl]. If such a rejection is made, applicants can then consider whether filing a terminal disclaimer is appropriate or not." (*Id.*).

The issue with respect to this rejection is whether the Examiner established that instant claim 1 is patentably distinct from Kedl claim 1.

Principle of Law

An obviousness-type double patenting analysis entails two steps: (1) construction of the claims of the patent and the claim in the application to identify any differences, and (2) determination of whether the differences in subject matter between the claims render the claims patentably distinct. *See Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed Cir. 2001).

Analysis

In the Answer, the Examiner acknowledged mistakenly referencing US Patent No. 5,078,978 instead of US Patent No. 7,427,629 B2. (*See* Ans. 17). The Examiner also mistakenly referenced a claim from what appears to be an application rather than an issued patent. (*See* Ans. 12). Of greater consequence, the Examiner failed to conduct an obviousness-type double patenting analysis on the record. In particular, the Examiner has neither identified the differences between the Kedl patent claim 1and Appellants' claim 1, nor discussed whether any differences in the subject matter between the claims render the claims patentably distinct. *See Lilly*, 251 F.3d at 968. Consequently, we do not find that the Examiner has properly supported the rejection.

Accordingly, we reverse the obviousness-type double patenting rejection.

CONCLUSIONS OF LAW

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to prepare the drug-support complex disclosed by Langer using the IRM of Miller, Gerster or Slade as the drug.

Appellants have not established that the claimed invention provided unexpected results sufficient to rebut a prima facie case of obviousness.

The Examiner did not show that the combined prior art taught or suggested using a macromolecular support material having an average largest dimension of at least 1 nm.

The Examiner has not established on the record that instant claim 1 is patentably indistinct from Kedl claim 1.

SUMMARY

We affirm the rejection of claims 1, 3, 12 and 14 under 35 U.S.C. § 103(a) over Miller, Gerster, Slade and Langer;

we reverse the rejection of claim 11 under 35 U.S.C. § 103(a) over Miller, Gerster, Slade and Langer; and

we reverse the rejection of claim 1 on the ground of non-statutory obviousness-type double patenting as unpatentable over claim 1 of Kedl.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

lp

3M INNOVATIVE PROPERTIES COMPANY
PO BOX 33427
ST. PAUL MN 55133-3427